STATE OF CONNECTICUT

General Assembly

Substitute Bill No. 299

____SB00299INS__022709___

*AN ACT EXPANDING HEALTH INSURANCE COVERAGE FOR
ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS.*

Be it enacted by the Senate and House of Representatives in General
Assembly convened:

1   Section 1. (NEW) (*Effective January 1, 2010*) Each individual health
2   insurance policy providing coverage of the type specified in
3   subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general
4   statutes delivered, issued for delivery, renewed, amended or
5   continued in this state shall provide coverage for the routine patient
6   care costs associated with clinical trials for the treatment of serious or
7   life-threatening diseases. As used in this section, (1) "clinical trial for
8   the treatment of serious or life-threatening diseases" means an
9   organized, systematic, scientific study of therapies, tests or other
10   clinical interventions for purposes of treatment or palliation or
11   therapeutic intervention for the prevention of serious or life-
12   threatening diseases in human beings, other than a cancer clinical trial
13   in accordance with sections 38a-504a to 38a-504g, inclusive, of the
14   general statutes, and (2) "routine patient care costs" means (A)
15   coverage for medically necessary health care services that are incurred
16   as a result of the treatment being provided to the insured person for
17   purposes of such clinical trial that would otherwise be covered if such
18   services were not rendered pursuant to such clinical trial. Such services
19   shall include those rendered by a physician, diagnostic or laboratory
20   tests, hospitalization or other services provided to the patient during

21   the course of treatment in such clinical trial for a condition, or one of

22   its complications, that are consistent with the usual and customary

23   standard of care and would be covered if the insured person were not

24   enrolled in such clinical trial; and (B) coverage for routine patient care

25   costs incurred for drugs provided to the insured person, in accordance

26   with section 38a-492b of the general statutes, as amended by this act,

27   provided such drugs have been approved for sale by the federal Food

28   and Drug Administration.

29   Sec. 2. (NEW) (*Effective January 1, 2010*) Each group health insurance

30   policy providing coverage of the type specified in subdivisions (1), (2),

31   (4), (11) and (12) of section 38a-469 of the general statutes delivered,

32   issued for delivery, renewed, amended or continued in this state shall

33   provide coverage for the routine patient care costs associated with

34   clinical trials for the treatment of serious or life-threatening diseases.

35   As used in this section, (1) "clinical trial for the treatment of serious or

36   life-threatening diseases" means an organized, systematic, scientific

37   study of therapies, tests or other clinical interventions for purposes of

38   treatment or palliation or therapeutic intervention for the prevention

39   of serious or life-threatening diseases in human beings, other than a

40   cancer clinical trial in accordance with sections 38a-542a to 38a-542g,

41   inclusive, of the general statutes, and (2) "routine patient care costs"

42   means (A) coverage for medically necessary health care services that

43   are incurred as a result of the treatment being provided to the insured

44   person for purposes of such clinical trial that would otherwise be

45   covered if such services were not rendered pursuant to such clinical

46   trial. Such services shall include those rendered by a physician,

47   diagnostic or laboratory tests, hospitalization or other services

48   provided to the patient during the course of treatment in such clinical

49   trial for a condition, or one of its complications, that are consistent with

50   the usual and customary standard of care and would be covered if the

51   insured person were not enrolled in such clinical trial; and (B)

52   coverage for routine patient care costs incurred for drugs provided to

53   the insured person, in accordance with section 38a-518b of the general

54   statutes, as amended by this act, provided such drugs have been

55   approved for sale by the federal Food and Drug Administration.

56   Sec. 3. Section 38a-492b of the general statutes is repealed and the
57   following is substituted in lieu thereof (*Effective January 1, 2010*):

58   (a) Each individual health insurance policy delivered, issued for
59   delivery, **[**or**]** renewed, amended or continued in this state **[**on or after
60   October 1, 1994, which**]** that provides coverage for prescribed drugs
61   approved by the federal Food and Drug Administration for treatment
62   of certain types of cancer shall not exclude coverage of any such drug
63   on the basis that such drug has been prescribed for the treatment of a
64   type of cancer for which the drug has not been approved by the federal
65   Food and Drug Administration, provided the drug is recognized for
66   treatment of the specific type of cancer for which the drug has been
67   prescribed in one of the following established reference compendia: (1)
68   The U.S. Pharmacopoeia Drug Information Guide for the Health Care
69   Professional (USP DI); (2) The American Medical Association's Drug
70   Evaluations (AMA DE); or (3) The American Society of Hospital
71   Pharmacists' American Hospital Formulary Service Drug Information
72   (AHFS-DI).

73   (b) Nothing in subsection (a) of this section shall be construed to
74   require coverage for any experimental or investigational drugs or any
75   drug which the federal Food and Drug Administration has determined
76   to be contraindicated for treatment of the specific type of cancer for
77   which the drug has been prescribed.

78   (c) **[**Nothing**]** Except as provided in section 1 of this act, nothing in
79   this section shall be construed to create, impair, limit or modify
80   authority to provide reimbursement for drugs used in the treatment of
81   any other disease or condition.

82   Sec. 4. Section 38a-518b of the general statutes is repealed and the
83   following is substituted in lieu thereof (*Effective January 1, 2010*):

84   (a) Each group health insurance policy delivered, issued for
85   delivery, **[**or**]** renewed, amended or continued in this state **[**on or after

86 October 1, 1994, which**]** that provides coverage for prescribed drugs
87 approved by the federal Food and Drug Administration for treatment
88 of certain types of cancer shall not exclude coverage of any such drug
89 on the basis that such drug has been prescribed for the treatment of a
90 type of cancer for which the drug has not been approved by the federal
91 Food and Drug Administration, provided the drug is recognized for
92 treatment of the specific type of cancer for which the drug has been
93 prescribed in one of the following established reference compendia: (1)
94 The U.S. Pharmacopoeia Drug Information Guide for the Health Care
95 Professional (USP DI); (2) The American Medical Association's Drug
96 Evaluations (AMA DE); or (3) The American Society of Hospital
97 Pharmacists' American Hospital Formulary Service Drug Information
98 (AHFS-DI).

99   (b) Nothing in subsection (a) of this section shall be construed to
100 require coverage for any experimental or investigational drugs or any
101 drug which the federal Food and Drug Administration has determined
102 to be contraindicated for treatment of the specific type of cancer for
103 which the drug has been prescribed.

104   (c) **[**Nothing**]** Except as provided in section 2 of this act, nothing in
105 this section shall be construed to create, impair, limit or modify
106 authority to provide reimbursement for drugs used in the treatment of
107 any other disease or condition.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2010*	New section
Sec. 2	*January 1, 2010*	New section
Sec. 3	*January 1, 2010*	38a-492b
Sec. 4	*January 1, 2010*	38a-518b

Statement of Legislative Commissioners:
In sections 1 and 2, the comma after "cancer clinical trial" was moved to after "human beings" for statutory consistency.

INS   *Joint Favorable Subst.-LCO*